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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,955	10/18/2005	Qing Zhu	0149-P03068US00	1020
110	7590	09/04/2007		
DANN, DORFMAN, HERRELL & SKILLMAN			EXAMINER	
1601 MARKET STREET			SNYDER, STUART	
SUITE 2400				
PHILADELPHIA, PA 19103-2307			ART UNIT	PAPER NUMBER
			1648	
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			09/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/536,955	ZHU ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Stuart W. Snyder	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 June 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-9,11,13-18 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,14,15 and 23-26 is/are withdrawn from consideration.
- 5) Claim(s) 1,4-6,11,13,16-18,27 and 29 is/are allowed.
- 6) Claim(s) 9,20-22,28 and 30-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Amendment of claims 1, 9, and 11 in Applicants' filing of 6/27/2007 is acknowledged; cancellation of claims 2, 3, 10, 12 and 19 as well as addition of new claims 20-32 is further acknowledged. Claims 1, 4, 7-9, 11, 13, 16-18, 20-22, 27-32 are subject to examination herein; claims 7-8, 14-15, and 23-26 are withdrawn because they are drawn to unelected subject matter.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> ¶***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Rejection of claims 1 and 4-6 under 35 USC § 112, 1<sup>st</sup> ¶, New Matter is withdrawn in view of Applicants' amendments.

### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> ¶***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 20-22, 28, and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claim 20 is drawn to a cell line that replicates HCV, is derived from a human non-hepatic cell line and comprises "the RNA from a second cell line which comprises an HCV genome". Claim 20 is confusing. First, the phrase "the

"RNA from a second cell line" is indefinite. Does the phrase refer to all of the RNA of a second HCV-infected cell line including tRNA, mRNA, and rRNA in addition to HCV genomic RNA? If not all of the cellular and viral RNA obtained from the second cell line, what RNA obtained from the second cell line is necessary to make the claimed invention other than viral RNA? Therefore, it is not clear if claim 20 provides any actual limitation other than a human non-hepatic cell line that comprises and replicates HCV.

The following is suggested as a substitute for claim 20:

A hepatitis C virus (HCV) replicating cell line, wherein said cell line is a human non-hepatic cell line and wherein said cell line comprises genomic HCV RNA and has been transfected with total RNA from a second HCV-replicating human cell line.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Rejection of claim 1 under 35 USC §102(b) as being anticipated by Houghton, et al., Seipp, et al. or Kato, et al. is **withdrawn** in view of Applicant's amendment.
5. Rejection of claims 1, 4 and 5 under 35 USC §102(b) as being anticipated by Sasagawa, et al and Wu, et al. is **withdrawn** in view of Applicant's amendment.

Art Unit: 1648

6. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Kato, et al. (1993 BBRC). Claim 20 is drawn to a human, non-hepatic cell-line comprising RNA from a second cell line comprising an HCV genome. Kato, et al. specifically names MT2 cells as a cell line supporting HCV replication as evidenced by measuring HCV in the supernatant of infected cell cultures up to 30 days post-infection and the increasing approach to homogeneity of a hypervariable region of the HCV genome, to wit, HVRI. Furthermore, MT2 cells comprise mRNA and tRNA in common with other human cells lines including Huh-7 cells. Thus, Kato, et al. taught all of the limitations of claim 20.
7. Claims 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizumo, et al. (1995 ). Claims 20-22 are drawn to a HeLa cell-line comprising RNA from a second cell line comprising an HCV genome. Mizumo, et al. specifically names HeLa cells as a cell line supporting HCV replication as evidenced by accumulation of particles with diameters of 30 and 45 nm, assumed to correspond to non-enveloped core-like particles and enveloped particles, respectively. Furthermore, HeLa cells comprise mRNA and tRNA in common with other human cells lines including Huh-7 cells. Thus, Mizumo, et al. taught all of the limitations of claims 20-22.
8. Claims 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton, et al. (US Patent 6,096,541; Issued Aug. 1, 2000). Claims 20-22 are drawn to a HeLa cell-line comprising RNA from a second cell line comprising an HCV genome. Houghton, et al. specifically names HeLa cells as a cell line

supporting HCV replication (see paragraph 175. Furthermore, HeLa cells comprise mRNA and tRNA in common with other human cells lines including Huh-7 cells. Thus, Houghton, et al. taught all of the limitations of claims 20-22.

***Allowable Subject Matter***

9. Claims 1 and 4-6 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 11, 13 and 16-18, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I, III and IV as set forth in the Office action mailed on 12/18/2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

10. Claims 1, 4-6, 11, 13, 16-18, 27 and 29 are allowed.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS



MARY E. MOSHER, PH.D.  
PRIMARY EXAMINER